



United States
Department of
Agriculture

Food Safety
And Inspection
Service

Technical
Service
Center

Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR ICELAND SEPTEMBER 10 THROUGH SEPTEMBER 19, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Iceland's meat inspection system from September 10 through September 19, 2002. All four establishments certified to export meat to the United States were audited. All of these were slaughter establishments and all were conducting processing operations.

The last audit of the Iceland meat inspection system was conducted in October 2001. Five establishments were audited. One establishment was found to be unacceptable (Est. 40). One major concern that was reported at that time was that HACCP-implementation was deficient to some degree in all of the establishments.

Iceland is eligible to export beef, pork and sheep meat to the United States at this time.

From January through June 30, 2002, Iceland establishments exported nearly 15,000 pounds of lamb meat to the U.S. There were no port-of entry rejections during this period.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Iceland national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. All establishments certified to export to the U.S. were audited (Ests. 22, 23, 31 and 81). Establishment 40, which was de-listed during the last audit, chose not to apply for re-certification. The third part was conducted by on-site visits to establishments. The fourth was a visit to three laboratories, one performing analytical testing of field samples for the national residue testing program, and one for culturing field samples for the presence of microbiological contamination with *E. coli* and one for the analysis of samples for the excessive presence of heavy metals, viz. lead, mercury, cadmium and arsenic.

Iceland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/

processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all of the establishments audited. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for generic *E. coli*, are discussed later in this report.

As stated above, one major concern had been identified during the last audit of Iceland's meat inspection system conducted in October 2001. During this new audit, the auditor determined that the concern had been addressed and corrected with some problems still evident.

HACCP-implementation deficiencies had been found in all establishments visited during the October 2001 audit (Ests. 22, 23, 31, 40, and 81). During this new audit, implementation of the required HACCP programs was again found to be deficient, but to a much lesser degree, in all establishments visited (Ests. 22, 23, 31 and 81). Details are provided in the Slaughter/Processing Controls section later in this report.

Entrance Meeting

On September 10, an entrance meeting was held in the Reykjavik offices of the Iceland Meat Inspection Division of the Ministry of Agriculture, and was attended by Dr. Sigurður Örn Hansson, Chief of Iceland Meat Inspection; Mr. David E. Jaberg, Economic/Commercial Officer, U.S. Embassy and Dr. M. Douglas Parks, International Audit Staff Officer, USDA. Topics of discussion included the following:

1. Audit itinerary to include laboratories and establishments to be audited.
2. Animal disease status.
3. Last audit findings.
4. Compliance and enforcement of meat regulations.
5. Subjects to be covered on this audit (SSOP, HACCP, and generic *E. coli* testing).

6. The rating of establishments and the issuance of 30 day notices of intent to delist and the criteria for each category.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Iceland's inspection system in October 2001.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents. This records review was conducted at the headquarters or the inspection service or at a district or regional office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

One concern arose as a result the examination of these documents. There were no records of monthly reviews by District Veterinarians in the central office in Reykjavik.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Iceland as eligible to export meat products to the United States were full-time or part time Inspection Service employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Four establishments were certified to export meat products to the United States at the time this audit was conducted. All four establishments were visited for on-site audits. In all establishments visited, both Iceland inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories, *intra*-laboratory quality assurance procedures, including sample handling, and methodology.

There were three laboratories audited during this visit: the Institute of Experimental Pathology, University of Iceland, the Syni Laboratory and the Icelandic Fisheries Laboratory all located in Reykjavik. All three laboratories were audited on September 12, 2002. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

The check sample program met FSIS requirements.

Iceland's microbiological testing for *E. coli* was being performed in private and/or government laboratories. One of these, the Syni Laboratory, a private laboratory, was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories have been accredited/approved by the government and/or accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses are being reported to the government or simultaneously to the government and establishment.

Microbiological testing for *Salmonella* is not applicable in Iceland, as sheep products are the only meat products exported to the United States. Generic *E. coli* testing for minor species is done in private laboratories and in laboratories in the slaughter establishments.

Establishment Operations by Establishment Number

The following operations were being conducted in the four establishments:

Beef, sheep, swine and horse slaughter and boning – two establishments (23 and 81)

Beef, sheep and horse slaughter and boning – one establishment (22)

Sheep slaughter and boning—one establishment (31)

SANITATION CONTROLS

Based on the on-site audits of establishments, Iceland's inspection system had controls in place for water potability, chlorination procedures, back siphonage prevention, hand washing facilities, sanitizers, pest control program and monitoring, temperature control, lighting, operations work space, inspector work space, and ventilation.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with some variations as noted here:

1. Preventive action not recorded in Ests. 22 and 31.
2. Rail dirt found on carcasses in Ests. 23 and 81.
3. An area of common touch of exposed carcasses in the bleeding area in Ests. 22 and 31.

Cross-Contamination

1. After being sanitized, the weasand rod was contaminated by touching wool.

Product Handling and Storage

Meat products were found to be stored under sanitary conditions in all establishments.

Personnel Hygiene and Practices

The procedures for personnel hygiene were in place in all establishments and were effective.

The sanitation control findings that are of major concern and the proposed actions are as follows:

1. Condensate was falling on employees and exposed product in the slaughter department of Est. 23. The carcasses were trimmed and the condensate corrected.
2. The area of common touch at the bleeding station in Ests. 22 and 31 were to be corrected that day.
3. Preventive action not recorded in Ests. 22 and 31 was to be corrected immediately.
4. Rail dirt found on carcasses in cooler in Ests. 23 and 81 was trimmed and the cleaning schedule of the rails was increased in frequency

ANIMAL DISEASE CONTROLS

Iceland's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

All animals in Iceland have individual identification for trace back of disease and residue.

RESIDUE CONTROLS

Iceland's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Icelandic inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

There is mandatory individual animal identification soon after birth. Tags and ear cuts or notches insure trace back of any animal to its origin. There is almost no movement of livestock from farm to farm and it is closely regulated by Icelandic law. All antibiotics, vaccines and other chemicals are only sold on the veterinarian's prescription and each carries a withdrawal notice from the veterinarian. Each treatment is recorded in books. There are no central markets for livestock in Iceland so all are sold directly to the slaughtering establishment.

SLAUGHTER/PROCESSING CONTROLS

Iceland's inspection system had controls in place to ensure adequate ante-and post-mortem inspection procedures and dispositions, control and disposition of dead, dying, diseased or disabled animals, humane handling and slaughter and disposition of inedible materials generated in the establishments.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with the following exceptions:

1. In case of a CCP failure, the corrective action was not related back to the population, only to the sample in Ests. 22 and 81.
2. The hazard analysis was incomplete in Ests. 22 and 23.
3. Verification methods were not scheduled in the CCP in Est. 31.
4. Preventive action following a CCP failure was not recorded in Est. 81.

All of these deficiencies were corrected.

Testing for Generic *E. coli*

Iceland has adopted the FSIS regulatory requirements for generic *E. coli* testing.

All four of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Iceland domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Iceland's inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries

(i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Salmonella testing is not required in Iceland's establishments that are certified to export meat products to the United States because Iceland only exports meat from sheep and FSIS has not established *Salmonella* performance standards for sheep.

Species Verification Testing

At the time of this audit, Iceland was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed at irregular intervals by the Iceland equivalent of Circuit Supervisors and are called District Veterinarians. They also have duties other than meat inspection and most are in private practice too. All were veterinarians with several years of experience. The records of these reviews were not available in the establishment or in the central office in Reykjavik.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were usually announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers. They are done at irregular intervals often less frequently than each month.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, an in-depth review is done, and the results are reported to Dr. Sigurður Örn Hansson and Dr. Halldór Runolfsson, for evaluation and a plan is formulated for corrective actions and preventive measures.

Enforcement Activities

There have been no formal investigations regarding violations of the legislation of slaughtering, meat processing and meat handling under the jurisdiction of the Veterinary Services during the past year because no violations were revealed. There are no provisions in Icelandic legislation on meat and meat processing which prohibit persons, that have been prosecuted and found guilty of an offense to the legislation, to start working in the meat industry after having served their sentence.

Exit Meetings

An exit meeting was conducted in Reykjavik on September 19, 2002. The participants were: Dr. Halldór Runolfsson, Chief Veterinary Officer of Iceland; Dr. Sigurður Örn Hansson, Chief Meat Inspection; Ms. Borghildur Magnúsdóttir, Assistant Economic/Commercial Officer, U. S. Embassy and Dr. M. Douglas Parks, International Audit Staff Officer, USDA

The following topics were discussed:

1. Preventive action requirements in SSOP. These requirements will be incorporated into the plans of the U.S. Certified establishments.
2. HACCP implementation deficiencies to include hazard analysis. The corrections will be incorporated into all HACCP plans.
3. Supervisor's monthly reports. These will begin immediately and will be filed in the establishment and the central office.
4. Sanitation problems to include rail dirt on carcasses, dressing faults, areas of common touch, and condensate. These deficiencies were corrected immediately.
5. Inspection faults. Adrenal glands, healed broken leg and feces and an abscess on carcasses in the cooler after the inspection station. These problems will be brought to the attention of the district veterinarian and the inspectors will be re-trained.

CONCLUSION

The inspection system of Iceland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Most of the concerns noted in the HACCP programs were corrected, as were the deviations in the SSOP program. For the concerns that could not be corrected immediately, commitments were forthcoming from Iceland officials to correct all of these deviations as soon as possible. Three of the four audited establishments were issued 30-day notices of intent to delist by Iceland Inspection. The notices detailed the deviations that had not been immediately corrected. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. M. Douglas Parks
International Audit Staff Officer

(Signed) Dr. M. Douglas Parks

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing
- D. Data collection instrument for *Salmonella* testing (*not applicable*)
- E. Laboratory Audit Form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
81	√	√	√	√	√	√	√	√
31	√	√	√	√	√	√	√	√
23	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
81	√	√	√	√	√	√	no	√	√	√	√	√
31	√	√	√	√	√	√	√	no	√	√	√	√
23	√	no	√	√	√	√	√	√	√	√	√	√
22	√	no	√	√	√	√	no	√	√	no	√	√

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
81	√	√	√	√	√	√	√	√	√	√
31	√	√	√	√	√	√	√	√	√	√
23	√	√	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√	√	√